

PATENT COOPERATION TREATY

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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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13. Juni 2006

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NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY

(PCT Rule 71.1)

Date of mailing
(day/month/year)

12.06.2006

Applicant's or agent's file reference
P31986

IMPORTANT NOTIFICATION

International application No.
PCT/US2005/008010

International filing date (day/month/year)
10.03.2005

Priority date (day/month/year)
10.03.2004

Applicant

OMNI LIFE SCIENCE, INC. et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/I/B/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international
preliminary examining authority:



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PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P31986	FOR FURTHER ACTION		See Form PCT/IPEA416
International application No. PCT/US2005/008010	International filing date (day/month/year) 10.03.2005	Priority date (day/month/year) 10.03.2004	
International Patent Classification (IPC) or national classification and IPC INV. A61F5/01			
Applicant OMNI LIFE SCIENCE, INC. et al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (<i>sent to the applicant and to the International Bureau</i>) a total of 13 sheets, as follows:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input checked="" type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. <p>b. <input type="checkbox"/> (<i>sent to the International Bureau only</i>) a total of (indicate type and number of electronic carrier(s)), containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input checked="" type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application 			
Date of submission of the demand 10.01.2006	Date of completion of this report 12.06.2006		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel: +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Josten, S Telephone No. +49 89 2399-2338		



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/US2005/008010

Box No. I Basis of the report

1. With regard to the language, this report is based on

- the international application in the language in which it was filed
- a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - international search (under Rules 12.3(a) and 23.1(b))
 - publication of the international application (under Rule 12.4(a))
 - international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements* of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

Description, Pages

1-19 as originally filed

Claims, Numbers

1-25 received on 23.05.2006 with letter of 19.05.2006

Drawings, Sheets

1/8-8/8 received on 23.06.2005

a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. The amendments have resulted in the cancellation of:

- the description, pages
- the claims, Nos.
- the drawings, sheets/figs
- the sequence listing (*specify*):
- any table(s) related to sequence listing (*specify*):

4. This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- the description, pages
- the claims, Nos. 8
- the drawings, sheets/figs
- the sequence listing (*specify*):
- any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-25
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-25
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-25
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

10/591966

IAP9 Rec'd PCT/PTO 07 SEP 2006

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Re Item I

Basis of the report

1. This IPER has been established as if the amendments to claim 8, i.e. the replacement of the wording "lower cuff" by the wording "resilient liner (46)" had not been made, since this amendment has no basis in the originally filed documents (Rule 70.2(c) PCT). As can be seen from the figures and the description the resilient liner 46 is formed by a plurality of discrete liner segments 49 and these liner segments are removably attached to either the upper cuff 22 or the lower cuff 25. However, there is no disclosure in the originally filed documents that the liner segments are removably attached to the resilient liner 46.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

2. Reference is made to the following documents:

- D1: US-A-4 938 207 (VARGO ET AL) 3 July 1990 (1990-07-03)
 - D2: DE 201 16 887 U1 (HEFELE, WILHELM JOSEPH) 28 February 2002 (2002-02-28)
 - D3: US 2003/187375 A1 (GAYLORD ERIC LEE) 2 October 2003 (2003-10-02)
 - D4: US-A-4 872 448 (JOHNSON, JR. ET AL) 10 October 1989 (1989-10-10)
 - D5: US-A-6 110 135 (MADOW ET AL) 29 August 2000 (2000-08-29)

3. The document D1 is regarded as being the closest prior art to the subject-matter of claim 1 and shows (the references applying to this document):

A knee brace for a user comprising:
a rigid arm 400, 420 (see Figure 7) having a hinge assembly 330 near a midpoint thereof;
a semi-rigid cuff assembly 350, 360 connected to said rigid arm and adapted to fit

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snugly about a leg of the user such that said hinge assembly is adjacent the user's knee; at least one strap 22, 24 for securing said knee brace to the user's knee; and a resilient liner having a plurality of discrete liner segments 50, 52, 54, 56, 58, 60, 62, 64, said resilient liner connected to an interior portion of said cuff assembly for providing a secure fit between said cuff assembly and the user's leg; said at least one liner segment is adapted to be secured between at least one of an upper cuff and a lower cuff of the cuff assembly and the thigh portion and calf portion, respectively, of the user.

Independent claim 1 differs from the disclosure of D1 in the feature that at least one of said plurality of discrete liner segments is removable.

One or more removable discrete liner segments 1, 1a, 2, 2a may be known from D2 (see the "Haftstreifen (3a)" fixed to the support members (3) in order to allow fixation of the liner segments). However, the man skilled in the art would not introduce this feature known from D2 into the knee brace known from D1 since such a combination would destroy the functionality of D1's knee brace.

Consequently, the subject-matter of claim 1 meets the requirements of novelty (Article 33(2) PCT) and inventive step (Article 33(3) PCT).

4. Claims 2 to 25 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Re Item VII

Certain defects in the international application

5. The independent claim should have been properly cast in the two-part form, with those features which in combination are known from D1 being placed in the preamble (Rule 6.3(b) PCT). Said two-part form would not render the claim less intelligible as can be seen from the above paragraph 3.